REMARKS

The Office has objected to the language and format of the Abstract. Applicant has amended the Abstract in order to comply with MPEP 608.01(b).

The Office has also objected to the specification because the status of U.S. Patent Application Serial No. 09/703,395 had not been updated to indicate that it had issued. Applicant has amended the specification in order to comply with 35 U.S.C. 120.

Claims Rejections - 35 USC §112 Second Paragraph

The Office rejected Claims 27, 31, 33, and 34 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. A §112 second paragraph rejection has two separate requirements, indefiniteness and failing to claim what applicant regards as the invention. With respect to indefiniteness, the "essential inquiry pertaining to this requirement is whether the claims set out and circumscribe a particular subject matter with a reasonable degree of clarity and particularity. Definiteness of claim language must be analyzed, not in a vacuum, but in light of (1) the content of the particular disclosure, (2) the teachings of the prior art, and (3) the claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made." (MPEP §2173.02).

A rejection stating that the claims fail to set forth the subject matter that the applicant regards as the invention is only appropriate where the applicant has stated that the invention is something different from what is defined by the claims (MPEP §2172(a)). There is a presumption that the claims describe the applicant's invention, absent evidence to the contrary.

The Office has rejected claims 31 and 33 as being unclear for the recitation "on a daily basis". Applicant has amended claims 31 and 33 to indicate that the digestive enzymes are administered with each meal thus clarifying how many times per day the tablet is taken by the individual.

The Office further rejected claim 33 as being unclear for the recitation "an amount is determined according to the age of the individual". Applicant has amended claim 33 to indicate that the "amount" is the "effective amount" of claim 23 and that the effective amount is determined by the age and weight of the individual.

The Office also rejected claim 34 as being unclear for the recitation "at least about three times per day". Applicant has amended claim 34 to delete the term "about".

Applicant believes the claims now particularly point out and distinctly claim the subject matter which Applicant regards as the claimed invention. Applicant states that the amendments to the claims do not add new subject matter. Accordingly, Applicant respectfully requests the Office to withdraw this rejection.

Claims Rejections - 35 USC §112 First Paragraph

The first paragraph of 35 U.S.C. 112 provides:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention. [emphasis added].

This section of the statute requires that the specification include the following:

(A) A written description of the invention;

(B) The manner and process of making and using the invention (the enablement requirement); and

(C) The best mode contemplated by the inventor of carrying out his invention.

MPEP §2161

The Office has rejected claims 23-35 and 42 under 35 U.S.C. 112, first paragraph as not providing enablement for a method for treating any and all individuals having an autistic disorder, just those having an autistic disorder with pathologic fecal chymotrypsin levels. Applicant has amended independent claims 23 and 42 to indicate a method for treating

individuals having an autistic disorder characterized by an abnormal fecal chymotrypsin level and a lack of protein digestion. As claims 24-35 depend from independent claim 23, Applicant respectfully submits that these rejection of these claims is now moot in light of the amendment to claim 23.

Applicant believes the claims are now enabling to one skilled in the art to which it pertains to use the invention commensurate in scope with these claims. Applicant states that the amendments to the claims do not add new subject matter. Accordingly, Applicant respectfully requests the Office to withdraw this rejection.

Telephone Interview

Present Office policy places great emphasis on telephone interviews initiated by the examiner. For this reason, it is not necessary for an attorney to request a telephone interview. Examiners are not required to note or acknowledge requests for telephone calls or state reasons why such proposed telephone interviews would not be considered effective to advance prosecution. However, it is desirable for an attorney to call the examiner if the attorney feels the call will be beneficial to advance prosecution of the application. MPEP §408.

Applicant believes the above amendments and remarks to be fully responsive to the Office Action, thereby placing this application in condition for allowance. No new matter is added. Applicant requests speedy reconsideration, and further requests that the Examiner contact its attorney by telephone, facsimile, or email for quickest resolution, if there are any remaining issues.

Respectfully submitted,

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